IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/805,864
Applicant:	Gary M. Johnson, *et al*
Filed:	March 22, 2004
Art Unit:	3767
Confirmation No.:	1803
Examiner:	Deanna K. Hall
Docket No :	A-3061-ALUS
Customer No :	21378

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF UNDER 37 C.F.R. 41.37

Sir:

In accordance with the Notice of Appeal filed February 3, 2010, Applicants submit this Appeal Brief, which is timely filed by April 5, 2010 because April 3, 2010 falls on a weekend.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest is Applied Medical Resources Corp.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences for this application

III. STATUS OF CLAIMS

Claims 1–22, 25, 26, and 36–50 are pending. Claims 23, 24, and 27–35 have been canceled. Claims 1–4, 6, 8–13, 16, 25, 26, and 40–44 stand rejected. Claims 5, 7, 14, 15, 17–22, 36–39, and 45–50 are withdrawn from consideration. Claims 1–22, 25, 26, and 36–50 are appealed.

IV. STATUS OF AMENDMENTS

No amendments were filed after the final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

None of the appealed claims is a means- or step-plus-function claim.

Independent claims 1, 6, and 44 are directed to a surgical access port **40** that is insertable through a body wall without the need for an obturator. Specification at p. 9, ll. 21–22; FIG **4**, **11**, **12**. The illustrated embodiment of the surgical access port **40** comprises a tubular cannula **42**, a seal housing **44** disposed at a proximal end of the cannula **42**, and a tissue-penetrating tip **48** disposed at a distal end of the cannula **42**. Specification at p. 9, ll. 18–21; p. 10, ll 6–8. As illustrated in FIGS. **5** and **6**, the tip **48** is coaxial with the cannula **42** during insertion of the surgical access port **40** through a body wall and into a body cavity. Specification at p. 10, ll. 12–17. After the tip **48** completes traversing the body wall and enters the body cavity, the tip **48** repositions itself to one side of the cannula **42**, swinging open, thereby opening the distal end of the cannula **42** as illustrated in FIG. **7**. Specification at p. 10, ll. 18–20. In this open configuration, surgical instruments may be inserted into the body cavity through the cannula **42**. Removal of the surgical access port **40** is illustrated in FIGS. **8–10**, which illustrates that the tip **48** realigns with the axial axis on withdrawal. Specification at p. 10, l. 20–p. 11, l. 2.

Referring to the embodiment illustrated in FIGS. **11** and **12**, independent claim 1 recites a surgical access port **40** for insertion into a body cavity, the surgical access port **40** comprising an

elongate tubular body **42**, and a tissue penetrating tip **48** connected to and disposed at a distal end of the tubular body **42**. Specification at p. 11, ll. 9–11. The elongate tubular body **42** comprises a lumen dimensioned for passage of surgical instruments therethrough. Specification at 11, ll. 11–13. The tip **48** has a first, penetrating position illustrated in FIG. **12** in which the tip **48** blocks the lumen of the elongate tubular body **42**. As discussed above, the tip **48** assumes the first position when penetrating a body wall. The tip **48** has a second, retaining position illustrated in FIG. **11** in which the tip **48** swings away from the elongate tubular body **42**, thereby unblocking the lumen of the elongate tubular body **42**. As discussed above, the tip **48** assumes the second position when the body wall has been traversed

Claims 2–5, 7, 8, 12–22, 25, 26, 36–43 are directly or indirectly dependent on claim 1.

Claim 2 recites that the surgical access port **40** further comprises a seal housing **44** operably connected to a proximal end of the elongate tubular body **42**. Specification at p. 11, ll. 9–11. The seal housing **44** comprises an access port **46** that permits passage of surgical instruments into the elongate tubular body **42**. Specification at p. 9, ll. 18–21; FIGS. **11, 12**.

Claim 3 provides a tip **48** that is sharp, pointed, or bladed. Specification at p. 10, l. 8.

Claim 4 provides a tip **48** that is substantially blunt or has a conical surface. Specification at p. 10, ll. 9–11.

Claim 8 provides that the tip **48** repositions to one side of the elongate tubular body **42** when no axial load is present to hold it in axial alignment with the elongate tubular body **42**. Specification at p. 11, l. 20–p. 12, l. 2.

Claim 12 provides that the elongate tubular body **42** is a thin-walled tube, sized and configured to allow passage of surgical instruments through the body wall an into the body cavity. Specification at p. 11, ll. 11–13.

Claim 13 provides that the tip **48** comprises a conical, tapered, or rounded shape to separate tissue layers and to provide a small fascial defect through which the tubular body can pass. Specification at p. 11, ll. 16–18.

Claim 16 provides at least one of the elongate tubular body **42** and tip **48** is formed from an optically clear material. Specification at p. 5, ll. 18–19; claim 16-as-filed.

Claim 25 depends on claim 4 and provides that the conical surface of the tip **48** facilitates insertion of the surgical access port **40** with a reduced penetration force and minimizes tenting of the body wall. Specification at p. 5, ll. 20–22.

Claim 26 depends on claim 4 and provides that the conical surface of the tip **48** facilitates separation of different layers of the body wall and provides proper alignment of the tip **48** between the layers. Specification at p. 5, l. 22–p. 6, l. 2.

Claim 40 provides that the tip **48** in the first, penetrating position blocks passage of an opening at the distal end of the elongate tubular body **42**, thereby preventing passage of surgical instruments through the elongate tubular body **42**. FIG. **12**.

Claim 41 is dependent on claim 40 and provides that the tip **48** in the second, retaining position, unblocks passage of the opening at the distal end of the elongate tubular body **42**, thereby allowing passage of surgical instruments through and out the elongate tubular body **42**.

Claim 42 provides that the tip **48** is a non-expanding tip. Specification at p. 12, ll. 2–6; FIGS. **20A–20C**.

Claim 43 provides that the tip **48** is a non-compressible tip.

Referring again to the embodiment illustrated in FIGS. **11** and **12**, independent claim 6 provides a surgical access port **40** for insertion into a body cavity, the surgical access port **40** comprising an elongate tubular body **42**, and a tissue penetrating tip **48** disposed at a distal end of the elongate tubular body **42**. Specification at p. 11, ll. 9–11. As discussed above, the tip **48** moves from a first, penetrating position to a second, retaining position. The tip **48** is generally conical. Specification at p. 11, ll. 16–18. The tip **48** repositions to one side of the elongate tubular body **42** in the second, retaining position. Specification at p. 10, ll. 18–20.

Claims 9–11 are dependent on claim 6.

Claim 9 provides that the repositioned tip **48** remains in an off-axis condition until removal of the surgical access port **40**. Specification at p. 10, ll. 20–21; FIG. 7.

Claim 10 provides that the repositioned tip **48** remains in a substantially right-angled condition. Specification at p. 10, ll. 20–21; FIG. 7.

Claim 11 provides that the tip **48** automatically realigns with the axis of the elongate tubular body **42** as the surgical access port **40** is withdrawn from the body wall. Specification at p. 10, l. 21–p. 11, l. 1; FIG. **8**.

Independent claim 44 provides a surgical access port **40** for insertion into a body cavity, the surgical access port **40** comprising an elongate tubular body **42** and a tip **48** connected to and disposed at a distal end of the elongate tubular body **42**. Specification at p. 11, ll. 9–11. The elongate tubular body **42** comprises a lumen dimensioned for passage of surgical instruments therethrough. Specification at 11, ll. 11–13. The tip **48** has a first, penetrating position illustrated in FIG. **12** in which the tip **48** blocks the lumen of the elongate tubular body **42**. As discussed above, the tip **48** assumes the first position when penetrating a body wall. The tip **48** has a second, retaining position illustrated in FIG. **11** in which the tip **48** swings away from the elongate tubular body **42**, thereby unblocking the lumen of the elongate tubular body **42**. As discussed above, the tip **48** assumes the second position when the body wall has been traversed. The tip **48** is a single-piece tip. Specification at p. 12, ll. 2–6; FIGS. **20A**.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Rejections Under 35 U.S.C. § 102

Claims 1, 3, 8, 12, and 40–44 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 7,422,572 (Popov).

The Examiner states that "Popov discloses a surgical access port comprising: [a]n elongate tubular body 8 having a lumen 10 and a tissue penetrating tip 31 connected to and disposed at the distal end of the tubular body capable of penetrating through a body wall; the tip in a first, penetrating position blocks the lumen of the elongate body, and the tip is capable of swinging from the first, penetrating position to a second, retaining position to unblock the lumen of the elongate body," citing FIGS. **8** and **9** of Popov. Final Office Action at 2 (Nov. 4, 2009).

The Examiner cites FIG. **9** of Popov as disclosing a sharp, pointed, or bladed tip. *Id.* at 3.

The Examiner characterizes the tip of Popov as capable of repositioning to one side of the tubular body when no axial load is present. *Id.*

The Examiner states that the tip of Popov is cabable of being a non-expanding tip or a non-compressible tip. The Examiner cites FIG. **3** of Popov as disclosing a single-piece tip. *Id.*

The Examiner characterizes the lumen **10** of Popov as dimensioned for the passage of surgical instruments **2**. *Id.*

B. Rejections Under 35 U.S.C. § 103

Claims 2, 4, 6, 9–11, 13, 16, 25, and 26 stand rejected under 35 U.S.C. § 103(a).

1. Rejections over Popov and Roth

Claims 2, 4, 6, 9–11, 13, 25, and 26 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Popov in view of U.S. Patent No. 5,626,598 (Roth). *Id.*

The Examiner characterizes Popov as disclosing the invention substantially as claimed, except for not disclosing that the tip of the tubular body is substantially blunt or conical. *Id.* The Examiner states that Roth is analogous art, and cites FIGS. **8**, **10**, **12**, **14**, **16**, **18**, and **20** of Roth as disclosing blunt or conical tips. *Id.* The Examiner reasons that modifying the device of Popov with the blunt or conical tip of Roth reduces penetration force when entering body tissue. *Id.* The Examiner further cites FIG. **20** of Roth as disclosing a conical, tapered, or rounded shape capable of separating tissue layers. *Id.* at 3–4.

The Examiner characterizes the tip of Popov as capable of remaining in an off-axis state until the access port is removed, whereupon the tip is capable of realigning with the axis of the tubular body. *Id.* at 4. The Examiner states that the repositioned tip is capable of remaining in a substantially right-angled condition. *Id.*

The Examiner states that Popov discloses a surgical instrument **2** enclosed in a tubular body **8**, but does not disclose a port with an opening sealed by a seal housing, and opening into the tubular body to allow passage of surgical instruments therethrough. *Id.* The Examiner cites col. 6, ll. 30–34 of Roth as disclosing this feature. *Id.* The Examiner reasons that modifying the device of Popov with the seal housing of Roth would seal the opening when surgical instruments are passed therethrough. *Id.*

2. Rejections over Popov

Claim 16 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Popov. *Id.*

The Examiner characterizes Popov as disclosing a tubular body **8** having a tip **31**. *Id.* The Examiner states that Applicants have not disclosed any problem solved by or any purpose for forming at least one of the tubular body and tip from an optically clear material. *Id.* The

Examiner further states that the tubular body and tip of Popov would perform equally well if formed from any material *Id* The Examiner characterizes forming at least one of the tubular body and tip from an optically clear material as a design consideration that fails to patentably distinguish over Popov. *Id* at 5.

3. Response to Arguments

The Examiner characterizes "tissue penetrating tip" as a recitation of intended use, which must result in a structural difference to distinguish from the cited art. *Id.* In response, the Examiner states that the lid **31** is capable of penetrating a body wall into a body cavity. *Id*

The Examiner refers to an edge **15** illustrated in FIG. **1** as sharp or pointed. *Id*

VII. ARGUMENT

A. Rejections Under 35 U.S.C. § 102

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987).

Claims 1, 3, 8, 12, and 40–44 stand rejected under 35 U.S.C. § 102(e) as anticipated by Popov. Popov discloses a compact catheter insertion apparatus. Popov at 7:48. Among the functions of catheter insertion devices is prevention of inadvertent needle sticks or pricks. Popov at 1: 29–32 ("To prevent the user from being pricked, the withdrawn needle is transposed into the protection position avoiding the transmission of the infection by the blood contaminated needle.")

1. Popov Does Not Disclose Every Feature Recited in Independent Claim 1

Independent claim 1 is not anticipated by Popov because Popov does not expressly or inherently disclose every feature recited in claim 1.

a. Popov Does Not Disclose an Elongate Tubular Body

Claim 1 recites in part "an elongate tubular body" The Examiner characterizes a handle **8** of Popov as corresponding to the recited "elongate tubular body". Final Office Action at 2 (Nov. 4, 2009). As best viewed in FIG. **2** of Popov, reproduced below, as well as in FIGS. **8** and **9** cited by the Examiner, the handle **8** comprises a longitudinal slot **29** that extends nearly the entire length of the handle **8**, from a proximal (left) end of the handle **8** to near a distal end (right) end. Popov at 9:58–63; FIGS. **2**, **3**, **6–9**

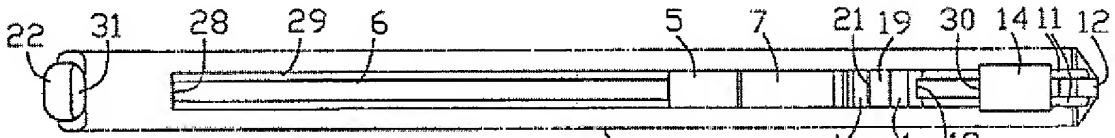

FIG.2

The longitudinal slot **29** gives the handle **8** a C-shaped cross section as best viewed in FIG. **5** of Popov (below), and as such, is an open channel rather than a tube, which has a closed cross section. Consequently, the handle **8** is not "tubular" as recited in claim 1. To the extent that

the left-most portion of the handle might be construed as "tubular", the left-most portion is not "elongate" as recited in claim 1.

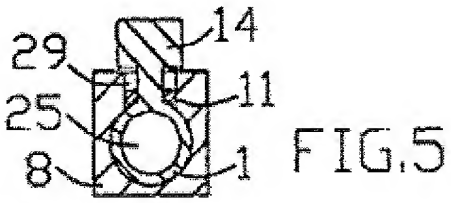

FIG.5

b. Popov Does Not Disclose a Lumen Dimensioned for the Passage of Surgical Instruments Therethrough

Claim 1 recites in part "the lumen is dimensioned for the passage of surgical instruments therethrough". The Examiner characterizes a security zone **10** illustrated in FIGS. **8** and **9** of Popov as corresponding to the "lumen". Applicants believe that the security zone **10** refers to a distal portion of an internal cavity **32** that extends the entire length of the handle **8**. Popov at 9:58–63; FIGS. **3**, **6–9**. Consequently, the present discuss refers to the internal cavity **32** rather than the security zone **10** of Popov, although it is equally applicable to both structures

The Examiner refers to a needle **2** as corresponding to the recited "surgical instrument". The needle **2** is a component of a needle unit **1**. Popov at 7:49 ("The compact catheter insertion apparatus shown in FIGS. **1** to **9** is comprised of: a needle unit **1** with a needle **2**"). While the needle unit **1** and needle **2** are translatable back-and-forth in the internal cavity **32**, neither the needle unit **1** nor the associated needle **2** pass *through* the internal cavity **32** because of the movement limiting elements discussed below that capture the needle unit **1** in the internal cavity **32**. Consequently, if the needle **2** corresponds to the "surgical instrument", the needle **2**, as a component of the needle unit **1**, cannot pass *through* the internal cavity **32**.

The needle unit **1** is disposed within the internal cavity **32**. Popov at 9:58–63 ("Handle **8** of the apparatus presents an oblong body with internal cavity **32** of a circular cross section, which houses needle unit **1** and catheter unit **5** in the transport position, serves as a guide for needle hub **4**, and has longitudinal slot **29** for movable location and the transposition of transposing member **14**."); FIGS. **2**, **3**, **5–8**. As best seen in FIGS. **6** and **7** of Popov, the insertion apparatus comprises a distal limiting member **28** that prevents the needle unit **1** from going out the distal end of the handle **8**. Popov at 9:38–42. The apparatus also comprises a proximal lid **27** that prevents the

needle unit from going out the proximal end of the handle **8**, as best seen in FIGS. **8** and **9**. Consequently, the needle unit **1** is captured in the internal cavity **32** of the tube **8** by the distal limiting member **28** and the proximal lid **27**. Moreover, the distal limiting member **28** is integrated with the handle **8**, and therefore, cannot be circumvented.

The internal cavity **32** is also not dimensioned for passage of a surgical instrument *therethrough* in addition to the captured needle unit **1**. As best seen in FIG. **5** of Popov (above), the needle unit **1** substantially fills the internal cavity **32**. Consequently, the internal cavity **32** cannot simultaneously accommodate both the needle unit **1** and another surgical instrument attempting to pass through the internal cavity **32**.

Furthermore, the proximal lid **27** closes the proximal end of the handle **8**. Popov does not disclose that the proximal lid **27** is removable. Because the proximal lid **27** prevents instruments from being inserted into the proximal end of the handle **8**, instruments cannot be inserted through the handle **8** or the internal cavity **32**.

For at least the above reasons, Popov also does not disclose a "surgical access port" as recited in the preamble of claim 1.

c. Popov Does Not Disclose a Tissue Penetrating Tip

Claim 1 recites in part "a tissue penetrating tip". The Examiner refers to a lid **31** as corresponding to the "tissue penetrating tip", stating that "the lid **31** is capable of penetrating through a body wall and into a body cavity." Final Office Action at 2, 5 (Nov. 4, 2009). Claim 1 recites "a first, penetrating position" in which the tip "blocks the lumen". Claim 1 also recites "a second, retaining position", with "the tip swinging away from the elongate body unblocking the lumen". The Examiner refers to FIGS. **8** and **9** of Popov as disclosing the recited first and second positions, presumably with FIG. **9** corresponding to the first position and FIG. **8** corresponding to the second position.

i. Popov Does Not Disclose that the Lid Penetrates Tissue

Popov does not expressly disclose that the lid **31** penetrates tissue. The Examiner also has not met the burden of showing that the lid **31** inherently penetrates tissue. M.P.E.P. 2112(IV). Instead, the Examiner merely asserts that "the lid **31** is capable of penetrating through a body wall and into a body cavity." Final Office Action at 2, 5 (Nov. 4, 2009). "To establish inherency,

the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950–51 (Fed. Cir. 1999) (citations omitted). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

ii. The Lid Is Not Capable of Penetrating Tissue

One skilled in the art would also not understand that the lid **31** is capable of penetrating tissue. Popov discloses that inadvertent needle sticks and pricks are undesirable. Popov at 1:29–32. Inadvertent needle sticks are not only annoying, they can also spread infection and disease. *Id.* ("To prevent the user from being pricked, the withdrawn needle is transposed into the protection position *avoiding the transmission of the infection by the blood contaminated needle*.") (emphasis added). The insertion apparatus of Popov is designed to prevent inadvertent needle sticks. One skilled in the art would understand the design of the catheter insertion apparatus insures that not only will the needle **2** be protected to prevent needle sticks, but also that no other component of the apparatus will inadvertently stick or prick either a patient or a user. Consequently, one skilled in the art reading Popov would understand that the lid **31** does not stick or penetrate tissue.

In fact, the lid **31** itself specifically *prevents the needle 2* from inadvertently sticking a patient. Popov at 9:42–49 ("The above noted safety means presents distal lid **31** of handle **8,** which in the protection position is manually closed as it is shown in FIG. **9**. Lid **31** relates to the safety limiting means restricting the mobility of the needle distal sharp point and the access to it with the restrictive barriers. Lid **31** as a distal barrier prevents the needle distal sharp point from going outside security zone **10** in a distal direction."). Consequently, the lid **31** itself does not stick or penetrate tissue.

Furthermore, as shown in FIG. **9** of Popov, the lid **31** is nearly completely recessed into the distal end of the handle **8**, such that the distal- (left-) most portion of the apparatus is an edge **E** of the handle **8**, as illustrated below. Even if a user were to force the apparatus against a patient and somehow penetrate tissue, it is the edge **E** that would be penetrating tissue, not the lid **31**.

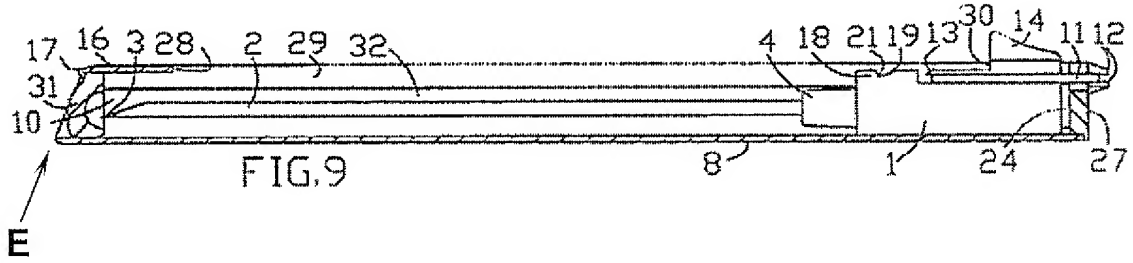

FIG. 9

2. Claims 3, 8, 12, and 40–43 Are Allowable as Dependent on Claim 1

Claims 3, 8, 12, and 40–43 are dependent on claim 1 and are allowable as dependent on an allowable base claim. Moreover, these claims further recite additional features not disclosed in Popov.

a. Claim 3: Popov Does Not Disclose a Sharp, Pointed, or Bladed Tip

Claim 3 is dependent on claim 1, and recites in part "the tip is sharp, pointed or bladed" The Examiner refers to a latch member **15** illustrated in FIG. **1** as an edge that is sharp or pointed. Final Office Action at 5 (Nov. 4, 2009). Popov does not expressly disclose that the latch member **15** is sharp or pointed. The Examiner also has not make the required showing that the latch member **15** is inherently sharp or pointed.

FIG. **1** below illustrates the latch member **15** as exposed in the illustrated configuration As discussed above, one skilled in the art would not understand any exposed component of the apparatus disclosed in Popov as potentially capable of causing inadvertent sticks or punctures to a patient. Consequently, one skilled in the art would not understand the latch member **15** as sharp or pointed.

FIG. 1

b. Claim 8: Popov Does Not Disclose the Tip Repositions to One Side Absent an Axial Load

Claim 8 recites in part "the tip repositions to one side of the tubular body when no axial load is present to hold it in axial alignment with the tubular body." The Examiner states, "The tip of Popov is capable of repositioning to one side of the tubular body when no axial load is present." Final Office Action at 3 (Nov. 4, 2009). The Examiner does not state that Popov expressly discloses the recited feature. The Examiner's bare assertion also does not meet the burden for an inherent disclosure.

Moreover, the lid **31** is not capable of *automatically* repositioning to one side absent an axial load as stated in claim 8. The lid **31** is *manually operated*. Popov at 9:42–44 ("The above noted safety means presents distal lid **31** of handle **8**, which in the protection position *is manually closed* as it is shown in FIG. **9** ") (emphasis added).[1] The Specification of the present application discloses a structure that *automatically* repositions the tip. Specification at p. 4, ll. 21–22 ("The retention member may be biased to hold the distal tip in an off-axis position when there is no axial load,") Popov does not disclose that the lid **31** automatically repositions.

c. Claim 12: Popov Does Not Disclose a Thin Walled Tube

Claim 12 recites in part "the tubular body is a thin walled tube sized and configured to allow passage of surgical instruments through the body wall an[d] into the body cavity." Popov does not expressly or inherently disclose any wall thickness of the handle **8**. Also, as discussed above, the handle **8** is not "tubular", and the internal cavity **32** does not allow passage of surgical instruments therethrough, either because the needle **2** itself does not pass through the internal cavity **32**, or because an instrument cannot pass by the needle insert **1** captured within the internal cavity **32**.

d. Claim 40: Popov Does Not Disclose a Tip Preventing Passage of Surgical Instruments

Claim 40 recites in part "the tip in the first, penetrating position blocks passage of an opening at the distal end of the elongate tubular body *preventing passage of surgical instruments through the elongate tubular body*." Popov does not disclose this feature expressly or inherently

As discussed above, surgical instruments are incapable of passing through the internal cavity **32**. Consequently, the lid **31** does not prevent passage of surgical instruments through the internal cavity **32**.

e. Claim 41: Popov Does Not Disclose Unblocking the Opening at the Distal End Allows Passage of Surgical Instruments

Claim 41 is dependent on claim 40 and recites in part "the tip in the second, retaining position, unblocks passage of the opening at the distal end of the elongate tubular body *allowing passage of surgical instruments through and out the tubular body*." Because surgical instruments cannot pass through the internal cavity **32**, as discussed above, the lid **31**, in the open position as illustrated in FIG. **8**, does nothing to permit passage of instruments through the internal cavity **32**.

f. Claim 42: Popov Does Not Disclose a Non-expanding Tip

Claim 42 recites in part "the tip is a non-expanding tip." The Examiner states that the tip of Popov is capable of being non-expanding Final Office Action at 3 (Nov 4, 2009). The Examiner does not state that Popov expressly discloses this feature. The Examiner also has not met the burden of showing that the tip (lid **31**) of Popov is inherently non-expanding.

g. Claim 43: Popov Does Not Disclose a Non-compressible Tip

Claim 42 recites in part "the tip is a non-compressible tip." The Examiner states that the tip of Popov is capable of being non-compressible. Final Office Action at 3 (Nov. 4, 2009). The Examiner does not state that Popov expressly discloses this feature. The Examiner also has not met the burden of showing that the tip (lid **31**) of Popov is inherently non-compressible.

3. Popov Does Not Disclose Every Feature Recited in Claim 44

As discussed above, Popov does not disclose the following features: "a surgical access port", "an elongate tubular body", "a lumen ... dimensioned for the passage of surgical instruments therethrough", and "a tip ... for penetrating through a body wall".

B. Rejections Under 35 U.S.C. § 103

Obviousness is a question of law based on underlying factual inquiries set forth in *Graham v. John Deere*: (1) determining the scope and content of the prior art; (2) ascertaining

---

[1] The lid **31** of the apparatus is in the open position until it is manually closed.

the differences between the claimed invention and the prior art; and (3) resolving the level of ordinary skill in the pertinent art. Objective evidence of non-obviousness must be also considered. In assessing the differences between the claim and the cited references, every feature of the claim must be disclosed or suggested in the cited references or known to one skilled in the art in making a *prima facie* case of obviousness. *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003). A *prima facie* case of obviousness also requires a reasonable expectation of success in the modification or combination of references, which must be found in the cited references or must be known to one skilled in the art. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Claims 2, 4, 6, 9–11, 13, 25, and 26 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Popov in view of Roth.

Claim 16 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Popov.

1. Independent Claim 6 Is Not Obvious over Popov and Roth

The Examiner relies on Popov for disclosing every feature recited in claim 6, except that the tip is generally conical, for which the Examiner relies on Roth.

a. Popov Does Not Disclose or Suggest the Features Relied on by the Examiner

As discussed above, Popov does not disclose the following features: "a surgical access port", "an elongate tubular body", the body "dimensioned for the passage of surgical instruments therethrough", and "a tissue penetrating tip".

b. Popov and Roth Would Not Be Combined As Proposed by the Examiner

The Examiner proposes "modif[ying] the device of Popov with the blunt or conical tip of Roth for entering the body tissue with a reduced penetration force." Final Office Action at 3 (Nov. 4, 2009). As discussed above, one skilled in the art would understand Popov as disclosing an apparatus that avoids unintentional or inadvertent pricks, cuts, or other tissue damage. Consequently, the catheter insertion apparatus of Popov would not be modified with an exposed tissue penetrating feature.

Popov at FIGS. **1–3, 6–9**. Popov does not disclose reopening a closed lid **31**.

2. Claims 9–11 Are Dependent Are Allowable as Dependent on Claim 6

Claims 9–11 are dependent on claim 6, and accordingly, are allowable as dependent on an allowable base claim. Moreover, these claims further recite additional features not disclosed or suggested in Popov or Roth.

a. Claim 9: Popov Does Not Disclose or Suggest a Repositioned Tip that Remains Off-Axis Until Removal of the Access Port

Claim 9 recites in part "the repositioned tip remains in an off-axis condition until removal of the access port." The Examiner states the "tip of Popov is capable of remaining in an off-axis conditions until removal of the access port". Final Office Action at 4 (Nov. 4, 2009). As discussed above, the apparatus of Popov does not penetrate tissue, and consequently, would not be "removed" as recited in claim 9. Even neglecting this deficiency for the sake of argument, Popov does not disclose or suggest that a position of the lid **31** depends on whether the catheter insertion apparatus is inserted through or removed from a body wall.

Although the Examiner does not rely on Roth for this feature, Roth also does not disclose or suggest this feature.

b. Claim 11: Popov Does Not Disclose or Suggest a Tip Automatically Realigns

Claim 11 recites in part "the tip automatically realigns with the axis of the tubular body as the access port is withdrawn from the body wall." The Examiner states the "tip of Popov ... is then capable of realigning with the axis of the tubular body." As discussed above in connection with claim 8, Popov does not disclose or suggest any *automatic* movement of the lid **31**. Consequently, nothing in Popov discloses or suggests that the lid **31** is capable of automatically realigning as discussed in claim 11. Roth also does not disclose or suggest this feature.

3. Claims 2, 4, 13, 25, and 26 Are Allowable as Dependent on Claim 1

Claims 2, 4, 13, 25, and 26 are directly or indirectly dependent on claim 1, and consequently, are allowable as dependent on an allowable base claim. These claims also recite additional features not disclosed or suggested in the cited references.

a. Claim 2 Is Not Obvious over Popov and Roth

Claim 2 recites in part "a seal housing operably connected to the proximal end of the tubular body, the seal housing having an access port providing an opening into the tubular body to allow passage of surgical instruments." The Examiner relies on Popov for disclosing every feature recited in claim 2 except for the seal housing, for which the Examiner relies on Roth.

i. Popov Does Not Disclose or Suggest the Relied-On Features

As discussed above, Popov does not disclose or suggest every feature recited in claim 1. Consequently, Popov also does not disclose or suggest antecedents for the following features recited in claim 2: "tubular body" and "passage of surgical instruments".

ii. Popov Would Not Be Modified by Roth as Proposed

The Examiner proposes modifying "the device of Popov with the seal housing as taught by Roth for sealing the opening when surgical instruments are passed through." One skilled in the art would not modify Popov with Roth as proposed by the Examiner. As discussed above, because the proximal end of the handle **8** of Popov is closed by a proximal lid **27**, instruments cannot be inserted into the proximal end of the handle **8**. Consequently, one skilled in the art would not operably connect a seal housing to the proximal end of the handle **8** as recited in claim 2 because there would be no point in providing a seal housing on a device through which instruments cannot be inserted.

4. Claim 16 Is Not Obvious Over Popov

Claim 16 recites in part "at least one of the tubular body and tip is formed from an optically clear material." The Examiner states, "Applicant has not disclosed that having at least one of the tubular body and tip formed from an optically clear material solves any stated problem or is for any particular purpose." Final Office Action at 4 (Nov. 4, 2009). The Specification of the present application discloses "The distal tip may be formed from a clear material to allow viewing through an endoscope during placement of the surgical access port." Specification at p. 5, ll. 18–19. Consequently, the clear tip solves the problem of blindly placing a trocar, and has a purpose of allowing viewing therethrough with an endoscope. Similarly, a clear tubular body permits visualization of the tissue or space adjacent to the tubular body.

In contrast, there is no purpose in manufacturing any of the components of Popov from an optically clear material because Popov does not disclose or suggest that the catheter introducer apparatus is placed with the assistance of an endoscope.

Claim 16 is also allowable as dependent on allowable claim 1.

C. Withdrawn Claims 5, 7, 14, 15, 17–22, 36–39, and 45–50 Should Be Rejoined and Allowed

The Examiner indicates that claims 1, 2, 6, 8–12, 16, 40, and 41 are generic. Election of Species Requirement at 2 (Jan. 10, 2008). Because claims 1, 2, 6, 8–12, 16, 40, and 41 are allowable over the references of record for at least the reasons provided above, withdrawn claims 5, 7, 14, 15, 17–22, 36–39, and 45–50 should be rejoined and found allowable as well M.P.E.P. 821.04(a).

D. Conclusion

Because each of the outstanding rejections of the appealed claims is overcome, Applicant requests that the Board find all appealed claims allowable over the references of record.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 01-2215.

Respectfully submitted,
APPLIED MEDICAL RESOURCES

BY _____
Pui Tong Ho
Registration No. 44,155
Telephone: (949) 713-8383

VIII. CLAIMS APPENDIX

The following is a listing of the claims on appeal.

1. (Previously presented) A surgical access port for insertion into a body cavity, comprising:

an elongate tubular body extending along an axis between a proximal end and a distal end, the elongate tubular body having a lumen extending between the proximal end and the distal end, wherein the lumen is dimensioned for the passage of surgical instruments therethrough; and

a tissue penetrating tip connected to and disposed at the distal end of the tubular body for penetrating through a body wall and into the body cavity, the tip in a first, penetrating position, blocks the lumen of the elongate body;

wherein the tip swings from the first, penetrating position to a second, retaining position, the tip swinging away from the elongate body unblocking the lumen of the elongate body, when the body wall has been traversed.

2. (Original) The surgical access port of Claim 1, further comprising a seal housing operably connected to the proximal end of the tubular body, the seal housing having an access port providing an opening into the tubular body to allow passage of surgical instruments

3. (Original) The surgical access port of Claim 1, wherein the tip is sharp, pointed or bladed.

4. (Original) The surgical access port of Claim 1, wherein the tip is substantially blunt or has a conical surface.

5. (Withdrawn) The surgical access port of Claim 1, further comprising a retention member for connecting the tubular body and the tip

6. (Previously presented) A surgical access port for insertion into a body cavity, comprising:

an elongate tubular body extending along an axis between a proximal end and a distal end, dimensioned for the passage of surgical instruments therethrough; and

a tissue penetrating tip disposed at the distal end of the tubular body for penetrating through a body wall and into the body cavity,

wherein the tip moves from a first, penetrating position to a second, retaining position,

wherein the tip is generally conical and repositions to one side of the tubular body in the second, retaining position.

7. (Withdrawn) The surgical access port of Claim 1, wherein the tip comprises at least two or more parts or petals that reposition to the side of the tubular body in the second, retaining position.

8. (Original) The surgical access port of Claim 1, wherein the tip repositions to one side of the tubular body when no axial load is present to hold it in axial alignment with the tubular body.

9. (Original) The surgical access port of Claim 6, wherein the repositioned tip remains in an off-axis condition until removal of the access port.

10. (Original) The surgical access port of Claim 6, wherein the repositioned tip remains in a substantially right-angled condition

11 (Original) The surgical access port of Claim 6, wherein the tip automatically realigns with the axis of the tubular body as the access port is withdrawn from the body wall.

12. (Original) The surgical access port of Claim 1, wherein the tubular body is a thin walled tube sized and configured to allow passage of surgical instruments through the body wall an into the body cavity.

13. (Original) The surgical access port of Claim 1, wherein the tip comprises a conical, tapered or rounded shape to separate tissue layers and to provide a small fascial defect through which the tubular body can pass.

14. (Withdrawn) The surgical access port of Claim 1, wherein the tip is solid or hollow.

15. (Withdrawn) The surgical access port of Claim 14, wherein the hollow tip is conical and operates as a specimen bag by closing on a specimen during removal of the access port.

16. (Original) The surgical access port of Claim 1, wherein at least one of the tubular body and tip is formed from an optically clear material.

17. (Withdrawn) The surgical access port of Claim 5, wherein the retention member is formed from metal or plastic.

18 (Withdrawn) The surgical access port of Claim 5, wherein the retention member operably connects with a sidewall of the tubular body.

19. (Withdrawn) The surgical access port of Claim 5, wherein the retention member is biased to hold the tip in an off-axis position when there is no axial load

20. (Withdrawn) The surgical access port of Claim 5, wherein the retention member is lightly held in axial alignment and subsequently deflected in the presence of an instrument within the tubular body.

21 (Withdrawn) The surgical access port of Claim 5, wherein the retention member is one of a spring, a spring wire, an offset hinge or a "living" hinge.

22. (Withdrawn) The surgical access port of Claim 5, wherein the retention member is formed from a substantially flat ribbon of metal.

23–24. (Canceled)

25. (Original) The surgical access port of Claim 4, wherein the conical surface facilitates insertion of the access port with a reduced penetration force and minimizes tenting of the body wall.

26. (Original) The surgical access port of Claim 4, wherein the conical surface facilitates separation of different layers of the body wall and provides proper alignment of the tip between the layers

27–35. (Canceled)

36. (Withdrawn) The surgical access port of claim 1 wherein the tip has a rounded centering portion extending from a proximal end of the tip and into the distal end of the elongate tubular body.

37. (Withdrawn) The surgical access port of claim 36 wherein a circumference of the rounded centering portion is equal to an inner circumference of the elongate tubular body.

38. (Withdrawn) The surgical access port of claim 5 wherein the tip has a plurality of proximally facing extensions dimensioned to fit into distally facing slots outlining an outer periphery of the tubular body.

39. (Withdrawn) The surgical access port of claim 38 wherein the retention member is fitted into the wall of the elongate tubular body and extends into the tip on one side of the tip that opposes the one of the plurality of proximally facing extensions and a remaining plurality of proximally facing extensions positioned therebetween.

40. (Previously presented) The surgical access port of claim 1 wherein the tip in the first, penetrating position blocks passage of an opening at the distal end of the elongate tubular body preventing passage of surgical instruments through the elongate tubular body.

41. (Previously presented) The surgical access port of claim 40 wherein the tip in the second, retaining position, unblocks passage of the opening at the distal end of the elongate tubular body allowing passage of surgical instruments through and out the tubular body.

42. (Previously presented) The surgical access port of claim 1 wherein the tip is a non-expanding tip.

43. (Previously presented) The surgical access port of claim 1 wherein the tip is a non-compressible tip.

44. (Previously presented) A surgical access port for insertion into a body cavity, comprising:

an elongate tubular body extending along an axis between a proximal end and a distal end, the elongate tubular body having a lumen extending between the proximal

end and the distal end, and dimensioned for the passage of surgical instruments therethrough; and

a tip connected to and disposed at the distal end of the tubular body for penetrating through a body wall and into the body cavity, the tip in a first, penetrating position, blocks the lumen of the elongate body;

wherein the tip swings from the first, penetrating position to a second, retaining position, the tip swinging away from the elongate body unblocking the lumen of the elongate body, when the body wall has been traversed, and

wherein the tip is a single-piece tip.

45. (Withdrawn) A surgical access port comprising:

a longitudinal axis;

an instrument access channel extending from a proximal and to a distal end thereof and substantially aligned with the longitudinal axis;

an elongate tubular body comprising a lumen through which the instrument access channel extends, the tubular body dimensioned for traversing a body wall into a body cavity;

a seal housing disposed at a proximal end of the tubular body;

a blunt, tissue penetrating tip; and

a retention member coupling the tip to a distal end of the tubular body,

wherein

the access port has a first configuration in which the tissue penetrating tip is substantially aligned with the longitudinal axis and substantially blocks the instrument access channel,

the access port has a second configuration in which the tissue penetrating tip is not aligned with the longitudinal axis and does not block and instrument access channel,

advancing the access port through tissue maintains the access port in the first configuration, and

the retention member biases the tip in the second configuration.

46. (Withdrawn) The surgical access port of claim 45, wherein the tissue penetrating tip separates tissue on advancement therethrough.

47. (Withdrawn) The surgical access port of claim 45, wherein the tissue penetrating tip is substantially frustoconical

48. (Withdrawn) The surgical access port of claim 45, wherein the tissue penetrating tip comprises a plurality of parts or petals.

49. (Withdrawn) The surgical access port of claim 45, wherein the tissue penetrating tip comprises a transparent material.

50. (Withdrawn) The surgical access port of claim 45, wherein the retention member comprises at least one of a spring, spring wire, offset hinge, and a living hinge.

IX. EVIDENCE APPENDIX

The references are relied on as evidence in this appeal: U.S. Patent No. 7,422,572 (Popov), and U.S. Patent No. 5,626,598 (Roth). Both Popov and Roth were both first cited in an Office Action dated August 8, 2008.

X. RELATED PROCEEDINGS APPENDIX

There are no related proceedings.